Supreme Court, U.S.
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No. _____

In The

Supreme Court of the United States

October Term, 1995

LYNNBROOK FARMS,
an Illinois General Partnership,

Petitioner,

v.

SMITHKLINE BEECHAM CORPORATION,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Are traditional state law causes of action seeking remedies for harm to livestock and other animals caused by unsafe and inefficacious animal vaccines preempted by an Animal and Plant Health Inspection Service ("APHIS") express declaration of preemption of state requirements which are different from, or in addition to, those imposed by the United States Department of Agriculture ("USDA") regarding the safety, efficacy, potency or purity of animal biologic products which are regulated by the USDA pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-159 (1913) (amended 1985) ("VSTA") and which have been licensed by APHIS, thus leaving injured plaintiffs without a remedy?

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PETITION FOR WRIT OF CERTIORARI

The Petitioner, Lynnbrook Farms, respectfully requests that a Writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Seventh Circuit entered in the present case on March 21, 1996, which held that state law damages claims were preempted as such claims were state requirements which were different from, or in addition to, requirements imposed by the United States Department of Agriculture ("USDA") under the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159 (1913)(amended 1985). App. D, A-39. A Writ of Certiorari is necessary in order to review the validity of the Seventh Circuit's decision.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit that gives rise to this petition appears at Appendix A to this petition (App. A, A-1) and is reported at 79 F.3d 620 (CA7 1996). By order filed April 22, 1996, the Seventh Circuit denied the petition for rehearing and suggestion for rehearing en banc, which order appears at Appendix C to this petition. App. C, A-38.

The opinion of the United States District Court for the Central District of Illinois, Peoria Division, appears at Appendix B to this petition (App. B, A-23) and is reported at 887 F.Supp. 1100 (C.D.Ill. 1995).

JURISDICTION

The judgment of the United States Court of Appeals for the Seventh Circuit was entered on March 21, 1996. App. A, A-1. On April 22, 1996, the Seventh Circuit denied Lynnbrook Farm's timely-filed petition for rehearing and suggestion for rehearing en banc. App. C, A-38. Pursuant to Supreme Court Rule 13.1, this Petition for a Writ of Certiorari has been filed within 90 days after the date of entry of the Seventh Circuit's order denying the petition for rehearing.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Appendix D sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. §§ 151-159 (1913) (amended 1985)(App. D, A-39); 9 C.F.R. § 112.2(b) (1991) (excerpt)(App. D, A-49); 57 Fed. Reg. 38758 (August 27, 1992)(App. D, A-50); S. Rep. No. 99-145, 99th Cong., 1st Sess. at 338-9 (1985)(App. D, A-45).

STATEMENT OF THE CASE

In clear conflict with the fundamental legal principles established by this Court in *Medtronic, Inc. v. Lohr*, Nos. 95-754 & 95-886, 1996 WL 345805 (U.S. June 26, 1996), the United States Court of Appeals for the Seventh Circuit held that an express declaration of preemption of state requirements which are different from, or in addition to, United States Department of Agriculture ("USDA") requirements, as stated in a Final Rule issued by the USDA's Animal and Plant Health Inspection Service ("APHIS") in 1992, preempts traditional state law claims for remedies relating to injuries caused by defective animal vaccines which have been licensed by APHIS pursuant to the Virus-Serum-Toxin Act ("VSTA"). *See generally* App. A, A-1; App. D, A-39,50. This petition now asks this Court to review a question of profound significance to all livestock producers, veterinarians, animal vaccine manufacturers, individual states, and the general consuming public, i.e., whether manufacturers may be held liable under traditional state laws for harm caused by dangerous, worthless, contaminated, harmful, unsafe, inefficacious or otherwise defective animal vaccines and analogous products which have been licensed by APHIS.

A. Background of Federal Regulation of Animal Vaccines

In 1913, Congress passed the Virus-Serum-Toxin Act ("VSTA") for the purpose of assuring the public that biologic products used in the treatment of animals are pure, safe, potent and efficacious. App. D, A-53,45. To achieve that goal, VSTA made it unlawful for any person, firm or

corporation to prepare or sell "any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals" and to prepare or sell any animal biologic product "unless and until [the product] shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license". 21 U.S.C. § 151 (1913)(amended 1985); App. D, A-39.

Congress adopted the 1985 amendments to VSTA for the purpose of bringing "intrastate" vaccines (i.e., vaccines produced and sold within a single state) under USDA control. App. D, A-45-48. Prior to the 1985 amendments to VSTA, intrastate vaccines could completely escape USDA regulation, while only those vaccines moving in interstate commerce were under the USDA's jurisdiction. *Id.* However, since most states did not actively regulate intrastate animal biologic products, those intrastate products were "almost entirely free of any official scrutiny in...33 states." *Id.* Recognizing the truly national markets and interstate movement of animal products as well as the need to assure "livestock owners, veterinarians and the American public that there is an ample supply of safe and effective animal vaccines and other biological products", Congress discarded the artificial distinction between interstate and intrastate vaccines and brought all animal biologic products under federal control via a single, uniform licensing system. *Id.* Neither VSTA nor its legislative history, however, makes any reference to concerns over common law product liability actions or whether Congress considered such actions to be a burden on the animal vaccine industry or on interstate commerce. *Id.*

Section 154 of VSTA authorizes the Secretary of Agriculture to issue and revoke licenses and to make such rules and regulations as may be necessary to prevent the preparation or sale of any worthless, contaminated, dangerous, or harmful animal vaccines or analogous products. 21 U.S.C. § 154 (amended 1985); App. D, A-40.

In reaction to the 1985 VSTA amendments, APHIS issued a Final Rule in 1992 declaring that:

> "...States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product."

See App. D, A-50,54.

B. Procedural Background Of The Present Case

The Petitioner, Lynnbrook Farms, filed this action in the United States District Court for the Central District of Illinois, Peoria Division, on May 18, 1994, seeking recovery against the Respondent, Smithkline Beecham Corporation, and its predecessor in interest, Norden Laboratories, upon traditional state law causes of action (i.e., strict liability, failure to warn, fraudulent misrepresentation and consumer fraud based on false advertising and promotion, and breach of implied warranties of merchantability and fitness). Lynnbrook Farms alleged that its cattle suffered injuries after they were vaccinated with USDA-licensed animal vaccines manufactured by Smithkline Beecham, namely *CattleMaster 4 and

Ultrabac 7/Somubac, and that those vaccines were inefficacious, unsafe, unreasonably dangerous, and defective.[1] The District Court had jurisdiction pursuant to 28 U.S.C. § 1332 based on diversity of citizenship with an amount in controversy in excess of $50,000. App. B, A-24.

On November 2, 1994, Respondent moved for summary judgment on all counts of Lynnbrook Farms' Amended Complaint claiming that Lynnbrook Farms' state law claims were preempted in their entirety by the aforesaid express declaration by APHIS. App. A, A-3. Implied preemption was not claimed by Smithkline Beecham. App. A, A-5 n.1. On March 30, 1995, the District Court, accepting as true the material allegations contained in Lynnbrook Farms' Amended Complaint, granted Smithkline Beecham's Motion for Summary Judgment and held that all of Lynnbrook Farms' state law claims were preempted by APHIS' declaration despite that the Court was "troubled by the absence of a federal remedy". App. B, A-24,37. On April 28, 1995, Lynnbrook Farms filed its Notice of Appeal.

On March 21, 1996, the United States Court of Appeals for the Seventh Circuit affirmed the decision of the District Court and held that APHIS' express declaration of preemption of state "requirements" encompassed all of

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[1] Lynnbrook Farms' complaint was filed against both Norden Laboratories and Smithkline Beecham, but suit continued only against Smithkline Beecham due to a merger on or about January 1, 1992 of Norden into Smithkline Beecham, Norden's successor in interest. *See* App. B, A-24.

Lynnbrook Farms' state law claims.

The Seventh Circuit based its decision that state "requirements" encompass state common law actions primarily on an analysis of the term "requirements" in this Court's opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), as well as in circuit court cases involving the same preemption language in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b), and in the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). The Seventh Circuit held that the language in these *statutes* was not distinguishable "in any meaningful way" from the language used in APHIS' *regulatory* declaration. App. A, A-14-17.

The Seventh Circuit, unlike the District Court below, did except from preemption, in dictum, any state law claims arising from non-compliance with USDA requirements. Simply because the vaccines involved in the present case were licensed by APHIS, however, the Seventh Circuit held that APHIS had declared these vaccines to be safe and efficacious and thus in compliance with its standards, thereby automatically precluding Lynnbrook Farms' state law claims. App. A, A-18. The Seventh Circuit, like the District Court, acknowledged that its conclusion would leave Lynnbrook Farms and similar consumers of licensed vaccines with "no remedy for the injuries and losses that they have suffered" resulting from such vaccines. App. A, A-21; App B, A-37.

On April 3, 1996, Lynnbrook Farms filed its petition for rehearing and suggestion for rehearing en banc which the Seventh Circuit then denied on April 22, 1996.

REASONS FOR GRANTING THE WRIT OF CERTIORARI

I.

The Seventh Circuit has Decided an Important Federal Question in a Way Which Conflicts With Relevant Decisions of This Court.

The Seventh Circuit based its finding of common-law preemption by APHIS primarily in the face of "strong and consistent authority" from numerous circuit courts interpreting the preemption language in the Medical Device Amendments ("MDA"). App. A, A-17. On June 26, 1996, however, this Court issued an Opinion relating to the MDA which establishes a clear conflict with the legal principles asserted by the Seventh Circuit in its judgment in the present case. *See Medtronic, Inc. v. Lohr*, Nos. 95-754 and 95-886, 1996 WL 345805 (U.S. June 26, 1996). Despite the statutory preemption language in the MDA, which is indistinguishable from APHIS's regulatory preemption declaration in this case, this Court, unlike the Seventh Circuit, allowed the plaintiffs' traditional state tort claims for remedies to survive. Granting of this petition is thus required by the clear conflict that exists between the Seventh Circuit's decision below and this Court's decision in *Medtronic*.

A. Conflict Regarding the Preemptive Scope of "State Requirements"

This Court's finding of no express preemption in the *Medtronic* case centered around the Congressional language

in the MDA which states as follows:

> "...no state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Medtronic, slip op., at 8-9 (opinion of Stevens, J.)(citing 21 U.S.C. § 360k).

Likewise, in the present case, the Seventh Circuit's finding of express preemption centered around APHIS' language in its 1992 Final Rule which states, in pertinent part, as follows:

> "...States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States."

App. A, A-7-8; App. D, A-50,54.

As it plainly appears from the foregoing excerpts and as already acknowledged by the Seventh Circuit below, the

language used in § 360k of the MDA and in APHIS' Final Rule is indistinguishable "in any meaningful way". App. A, A-17. However, this Court held that such language is insufficient to preempt state law causes of action, whereas, in conflict with this Court's decision, the Seventh Circuit held that such language is sufficient to preempt such claims. *Id.*; *Medtronic*, slip op. at 14-19 (opinion of Stevens, J.).

In clear conflict with the fundamental legal principles established by this Court in *Medtronic*, the Seventh Circuit held that it was "not persuaded" that the term "requirements" reflects only an intent to preempt state regulation or similar positive enactments, and instead held that state common law actions impose "additional requirements" on animal vaccines. App. A, A-14,17. To the contrary, this Court, in holding that the "singularly odd word" used by Congress, namely "requirement", was *not* sufficient to preclude all state common-law damages claims, stated that the word requirement "appears to presume that the State is imposing a specific duty upon the manufacturer", and since the use of the word "requirement" in the Federal Act "refer[s] only to statutory and regulatory law that exists pursuant to the [Federal Act] itself, [this] suggest[s] that the pre-empted "requirements" established or continued by states also refer primarily to positive enactments of state law." *Medtronic*, slip op. at 15, 17 (opinion of Stevens, J.)(emphasis added).

Moreover, the Seventh Circuit's decision that "APHIS' preemption statement is clear and comprehensive" is completely at odds with this Court's ruling in *Medtronic* which stated that the mirrored preemption provision in the MDA is "highly ambiguous" and does not clearly signal an "intent to

deprive states of any role in protecting consumers." App. A, A-13; *Medtronic*, slip op. at 3 (Breyer, J., concurring); *Medtronic*, slip op. at 17 (opinion of Stevens, J.). To the contrary, APHIS' own regulations actually evince the allowance of traditional state damages claims as indicated by the following APHIS regulation:

> "Labels...may not include disclaimers of merchantability, fitness..., or responsibility for the product."

9 C.F.R. § 112.2(b) (emphasis added); App. D, A-49. This regulation would have no meaning unless state law actions could be maintained.

On the issue of the preemptive scope of the term "requirements", the Seventh Circuit is also in conflict with this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), by interpreting the preemptive scope of that case much more broadly than intended by this Court. *Medtronic* makes it clear that the *Cipollone* case is not as far-reaching as the Seventh Circuit applied it below. *Cipollone* involved a statute with a much narrower preemptive effect on potential remedies than in the MDA and, likewise, than in the mirrored language of APHIS' Final Rule. *Medtronic*, slip op. at 15-17 (opinion of Stevens, J.). Unlike the statute which was involved in *Cipollone*, an interpretation of the word "requirements", as it is used in the MDA and in APHIS' Final Rule, to preempt state causes of action would "require far greater interference with state legal remedies [than in *Cipollone*], producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of

remedy". *Id.* Thus, in *Medtronic*, this Court rejected the manufacturer's argument therein "that by using the term "requirement", Congress clearly signaled its intent to deprive states of any role in protecting consumers from the dangers inherent in many medical devices." *Id.* at 16-17, 29 n.19. Rather, the lack of a remedy for injured parties was strong evidence that Congress could not have intended to preempt state actions for remedies. *Id.* at 14-15. The Seventh Circuit, therefore, is in direct conflict with the legal principles set forth by this Court in *Cipollone* and *Medtronic* by utilizing *Cipollone's* narrow interpretation of the term "requirements" to preempt consumers' remedies for defective animal vaccines.

In further conflict with *Cipollone* which held that the general common-law duties "not to deceive" and "not to make fraudulent statements" were not within the scope of "requirements", the Seventh Circuit expressly held that the term "requirements" does encompass claims for fraud. *Id.* at 29 n.19; App. A, A-20.

Lastly, it is even questionable whether the Seventh Circuit afforded proper weight to APHIS' declaration of preemption since even the dissenting Opinion in *Medtronic* stated that "it is not certain that an agency regulation determining the preemptive effect of any federal statute is entitled to deference. *Medtronic*, slip op. at 4 (O'Connor, J., concurring in part and dissenting in part)(emphasis added).

B. Conflict Relating to the Primary Purpose of VSTA and the MDA

Not only was the MDA's language at issue in *Medtronic* indistinguishable from the language at issue in the present case, but the similarity of purpose of the MDA and of VSTA is also quite evident, thus making the Seventh Circuit's decision even more in conflict with this Court's decision in *Medtronic*. Just as the purpose of VSTA "is to assure that biologics used in the treatment of animals are pure, safe, potent and efficacious", the MDA "was enacted to provide for the safety and effectiveness of medical devices intended for human use." App. D, A-45,53; *Medtronic*, slip op. at 17 (opinion of Stevens, J.)(citing 90 Stat. 539).

In *Medtronic*, this Court made "an examination of the basic purpose of the [MDA] as well as its history" and determined that, although there was some reflection of concerns to "protect innovations in device technology from being stifled by unnecessary restrictions", the legislative history indicated "that any fears regarding regulatory burdens were related more to the risk of additional federal and state regulation rather than the danger of pre-existing duties under common law." *Medtronic*, slip op. at 17-18 (opinion of Stevens, J.)(emphasis added). This Court discovered no reference in the MDA's legislative history of any fear that product liability actions would hamper the development of medical devices, and it held that any concern over such protection of the industry "was far outweighed by concerns about the primary issue motivating the MDA's enactment:

the safety of those who use medical devices." *Id.* (emphasis added).

Like the MDA, the legislative history of VSTA reflects absolutely no fear of state product liability actions hampering the innovation of animal vaccines or burdening interstate commerce in any manner. App. D, A-45. Rather, it is clear that the only purpose of the 1985 amendments to VSTA, other than the continued promotion of safety and efficacy, was to bring intrastate vaccines (i.e., vaccines produced and sold within a single state) under USDA control by discarding the artificial distinction between intrastate and interstate vaccines. Prior to the amendments, the "artificial distinction" allowed most intrastate vaccines to escape any official scrutiny. *Id.*

Despite the similarity in purpose of the MDA and VSTA, and despite the fact that VSTA, unlike the MDA, did not even make any reference to any need to protect product innovation, the Seventh Circuit, in clear conflict with this Court's decisions, found that claims relating to animal vaccines were preempted even though it failed to point to anything "in the hearings, the committee reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective [animal vaccines]." *Medtronic*, slip op. at 19 (opinion of Stevens, J.)(emphasis added); *See* App. A, A-7; *See also Silkwood v. Kerr-Mcgee Corp.*, 464 U.S. 238, 251 (1984). As stated by this Court, "if Congress intended such a result, its failure even to hint at it is spectacularly odd", and "[i]t is, to say the least, 'difficult to believe that Congress would,

without comment, remove all means of judicial recourse for those injured by illegal conduct'". *Medtronic*, slip op. at 19 (opinion of Stevens, J.); *Silkwood*, 464 U.S. at 251. The Seventh Circuit, however, in conflict with this Court's decisions, apparently did not require any such affirmative showing of Congressional intent to preempt state actions. Indeed, the opinion below, although recognizing the existence of the heightened presumption against the preemption of such actions, quickly disregarded and discounted the presumption's importance. App. A, A-12-13. *Cf. Medtronic*, slip op. at 19 (opinion of Stevens, J.); *Silkwood*, 464 U.S. at 251.

Even if APHIS intended to preempt state claims by the use of the term "requirements", such an action by APHIS would have been outside the scope of the authority delegated to the agency by Congress. Nothing in VSTA nor its legislative history expressly or impliedly suggests that Congress was at all concerned with state common law actions or the preemption thereof. App. D, A-39,45.

C. The Seventh Circuit's Ruling Relating to Compliance With Federal Regulations

Finally, the Seventh Circuit, in ruling that state common law actions were preempted by APHIS, essentially carved out, in dictum, an exception allowing some common law actions to survive if a case involves non-compliance with APHIS regulatory standards. App. A, A-17-19. A similar exception was found by the dissenting justices in the *Medtronic* case. *Medtronic*, slip op. at 5-6 (O'Connor, J., concurring in part and dissenting in part). Likewise, the

Seventh Circuit further held that "when all regulations are complied with and APHIS licenses the vaccine, it is clear that the vaccine satisfies APHIS standards for safety, purity, potency and efficacy", and, accordingly, "state tort claims involving the safety, efficacy, potency or purity of an animal vaccine do *not* survive." App.A, A-18-19.

The Seventh Circuit went on to hold that since Lynnbrook Farms had not alleged non-compliance in its complaint, that the vaccines at issue were thus in compliance with VSTA. App. A, A-18-20. However, as acknowledged by the Seventh Circuit, Lynnbrook Farms' complaint did allege that the vaccines were defective, unreasonably dangerous, unsafe and ineffective. App. A, A-20. These allegations were accepted as true by the Seventh Circuit, and, as stated by this Court in *Medtronic*, "although the precise contours of [the] theory of recovery have not yet been defined ([i.e., since] the pre-emption issue was decided on the basis of the pleadings [only]), it is clear that the...allegations may include claims that [the manufacturer] has, to the extent that they exist, violated [federal] regulations." *Medtronic*, slip op. at 23 (opinion of Stevens, J.). As a result, the Seventh Circuit, once again in conflict with this Court's decision in *Medtronic*, held that claims of non-compliance with federal regulations are not implied in allegations concerning state common law actions. App. A, A-20.

Lynnbrook Farms, like the plaintiffs in *Medtronic*, could not have specifically alleged non-compliance since there is no express or implied private cause of action based on violations of VSTA, just as no such actions exist in the MDA. *Medtronic*, slip op. at 14, 23 (opinion of Stevens,

J.). Furthermore, since the preemption issue in this case was decided at the pleading stage and since no discovery regarding compliance had yet been taken, Lynnbrook Farms had no ability on personal knowledge, other than by alleging in its complaint that the vaccines were unsafe and inefficacious, to develop a factual dispute regarding the compliance issue for summary judgment purposes. Nevertheless, the compliance question was a genuine issue of material fact because it was raised by the Petitioner's allegations which were accepted as true by the Seventh Circuit, thus precluding the award of summary judgment in favor of SmithKline Beecham. Moreover, an award of summary judgment in favor of Smithkline Beecham on the compliance issue essentially nullifies the "exception" to general tort preemption which the Seventh Circuit obstinately created since, in reality, few, if any, plaintiffs could ever survive summary judgment once proof of licensure is presented by a manufacturer.

Regardless, the Seventh Circuit's dependence on "compliance", as it relates to the preemption issue in the present case, even raises a conflict between the dissenting opinion in *Medtronic* and the Seventh Circuit's opinion, which both would preempt claims to the extent that there was compliance with federal regulations. Specifically, *statutory* construction strongly supports Petitioner's view that preemption in this case on the basis of compliance would be entirely inconsistent with the language of § 151 of VSTA. *See* App. D, A-39.

From the plainest meaning of § 151, it is abundantly clear that a corporation may be in violation of the statute for both preparing or selling any worthless, contaminated, dangerous or harmful vaccine ***and*** for preparing or selling a

vaccine that is not under and in compliance with APHIS regulations. In other words, it is undisputable from a fair reading of § 151 that even if a vaccine was prepared under and in compliance with APHIS regulations, a corporation can still be in violation of the statute for selling a vaccine that is worthless, contaminated, dangerous or harmful.

Even assuming that the Seventh Circuit was correct in holding that APHIS intended to preempt cases involving compliance with federal requirements, such an intent by the agency would have been arbitrary, capricious and manifestly contrary to the statute (i.e., § 151) which the agency was authorized to administer since that statute plainly does not exempt a corporation from liability for preparing or selling a worthless, contaminated, dangerous or harmful vaccine even though the vaccine may have been licensed by APHIS and prepared or sold under and in compliance with USDA regulations.

Such a clear Congressional statement concerning the role of compliance as it exists in VSTA does not even exist in the MDA at issue in the *Medtronic* case, yet this Court allowed the common law claims anyway for the reasons aforesaid, thus making even clearer the conflict between the Seventh Circuit's decision and this Court's decision (and even the dissenting Opinion of this Court) in the *Medtronic* case as Lynnbrook Farms' state law claims should have been allowed regardless of whether or not SmithKline Beecham's vaccines were in compliance with APHIS regulations.

D. Summary

Because of the numerous conflicts between the legal principles asserted by the Seventh Circuit's decision in the present case and the fundamental legal principles pronounced in the decisions of this Court, a correction by this Court of the Seventh Circuit's judgment is necessitated.

II.
The Seventh Circuit Has So Far Departed From the Accepted and Usual Course of Judicial Proceedings, and Sanctioned Such a Departure by a Lower Court, As To Call for an Exercise of this Court's Supervisory Power.

Prior to the 1995 District Court decision in the present case, the regulation of animal biologic products by the USDA had never before preempted consumer remedies for animal vaccine-related injuries. In fact, the validity and scope of APHIS' preemption declaration at issue in the Seventh Circuit was one of first impression at the circuit court level. App. A, A-3. Clearly, the District Court and Seventh Circuit decisions run counter to a long history of cases which have allowed such suits against animal vaccine manufacturers.[2]

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[2] *See, e.g., Vasgaard v. Smithkline Beecham Animal Health*, CIV 93-4029 (S.D.S.D. 1995)(decision of Judge John B. Jones denying in all respects Smithkline Beecham's motion for summary judgment based upon APHIS preemption); *Stange v. Norden Laboratories, Inc.*, CIV 91-

Thus, by preempting all traditional state law claims relating to animal vaccines, the Seventh Circuit has so far departed from the accepted and usual course of judicial proceedings in products liability cases, and has sanctioned such a departure by a lower court, as to call for this Court's supervisory power. This Court's guidance is clearly necessary in this case to return state products liability law in the animal vaccine regime to the status quo before *Lynnbrook Farms* and its progeny and to assure that livestock producers, veterinarians and other consumers are once again protected from dangerous and ineffective vaccines as was the original and paramount intent of Congress.

4125 (S.D.S.D.)(case also involving CattleMaster 4 vaccines wherein a jury instruction was given stating that "[c]ompliance with [USDA] Regulations is not, in and of itself, sufficient to exempt a manufacturer from liability..."). *See also Overstreet v. Norden Laboratories, Inc.*, 669 F.2d 1286 (CA6 1982); *Alman Brothers Farms & Feed Mill, Inc. v. Diamond Laboratories, Inc.*, 437 F.2d 1295 (CA5 1971); *Krupp v. Norden Laboratories, Inc.*, 393 N.W.2d 548 (Wis. 1986); *Van Wyk v. Norden Laboratories, Inc.*, 345 N.W.2d 81 (Iowa 1984); *Lovington Cattle Feeders, Inc. v. Abbott Laboratories*, 642 P.2d 167 (N.M. 1982); *Pearson v. Franklin Laboratories, Inc.*, 254 N.W.2d 133 (S.D. 1977); *Colorado Serum Co. v. Arp*, 504 P.2d 801 (Wyo. 1972); *Carter Farms Co. v. Hoffman-Laroche, Inc.*, 492 P.2d 1000 (N.M. 1971); *O.M. Franklin Serum Co. v. C.A. Hoover & Son*, 418 S.W.2d 482 (Tex. 1967); *Chandler v. Anchor Serum Co.*, 426 P.2d 82 (Kan. 1967); *Brown v. Globe Laboratories*, 84 N.W.2d 151 (Neb. 1957).

III.

The Seventh Circuit Has Decided An Important Question of Federal Law That Has Not Been, But Should Be, Settled By This Court.

By granting this petition, this Court could certainly resolve the scope of preemption concerning animal biologic products, and since the present case is now the leading case on the APHIS preemption issue in the United States, it is also the proper vehicle for defining the scope of preemption regarding such products. A decision by this Court in the present case will have widespread effects upon the entire nation as it would substantially impact state sovereignty, the livestock industry, the animal vaccine industry, veterinary medicine, and the consuming public. State civil remedies for injuries relating to all animal biologic products which are regulated by the USDA pursuant to VSTA make this a matter of critical importance not only to the parties involved but also, and more importantly, to all animal vaccine manufacturers, livestock farmers, veterinarians and the consuming public.

Clearly, this case presents an issue of vital importance: whether state law claims involving animal vaccines are preserved or are entirely foreclosed. The underlying issue, of course, is whether VSTA should be used as a preemptive sword for vaccine manufacturers or whether it should be utilized as a protective shield for farmers, veterinarians and the consuming public.

The present case provides this Court with an excellent

opportunity to resolve the scope of APHIS' declaration of preemption of state requirements and whether that declaration encompasses state law claims for remedies relating to injuries from animal biologic products. This is a case of profound significance, as a decision by this Court would affect all animal vaccines and other biologic products licensed under VSTA. Therefore, this Court should grant this petition to review the decision of the Seventh Circuit and to establish certainty in the nation concerning the scope of manufacturers' liability relating to these animal products.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for writ of certiorari.

Respectfully submitted,

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July 22, 1996

APPENDIX A

IN THE

UNITED STATES COURT OF APPEALS

FOR THE SEVENTH CIRCUIT

No. 95-2051
LYNNBROOK FARMS,

Plaintiff-Appellant,

v.

SMITHKLINE BEECHAM CORPORATION,

Defendants-Appellees.

Appeal from the United States District Court
for the Central District of Illinois, Peoria Division.
No. 94-C-1227 – Michael M. Mihm, *Judge.*

ARGUED OCTOBER 27, 1995 – DECIDED MARCH 21, 1996

Before FLAUM, ROVNER and EVANS, *Circuit Judges.*

FLAUM, *Circuit Judge.* This case requires us to determine whether certain state common law causes of action asserted against a manufacturer of animal vaccines are preempted by federal law. Plaintiff, Lynnbrook Farms ("Lynnbrook"), sued Smithkline Beecham Corporation ("SBC") alleging that its cattle were injured and many were killed after being inoculated with animal vaccines

manufactured by SBC. The district court granted summary judgment in favor of SBC, finding Lynnbrook's claims were preempted in their entirety by the United States Department of Agriculture's ("USDA") declaration of preemption issued through its Animal and Plant Health Inspection Service ("APHIS"). We affirm.

I.

The relevant facts are undisputed for purposes of our consideration of the preemption issue. The parties agree that we should accept as true the material allegations contained in Lynnbrook's complaint. In 1992, Lynnbrook vaccinated its cattle with two vaccines manufactured and sold by SBC – CattleMaster 4 and Ultrabac 7/Somubac. Lynnbrook followed all directions and correctly administered the vaccines. Both of the vaccines used by Lynnbrook were specifically licensed by APHIS, the agency charged by the USDA with regulating animal vaccines. 9 C.F.R. § 101.2. Lynnbrook employed the vaccines to prevent its cattle from contracting debilitating or mortal infections and diseases. Notwithstanding the inoculation of Lynnbrook's cattle with these vaccines, the cattle did contract infections and diseases that ultimately killed some of the cattle and debilitated others to an extent that Lynnbrook had to sell or dispose of them at a loss. We assume that the vaccines used were either not effective in preventing the maladies they were designed to guard against, or that the vaccines caused other harm to Lynnbrook's cattle.

Lynnbrook proceeded to sue SBC for the damages it incurred due to the loss of its cattle. Lynnbrook sought

recovery under theories of strict products liability, misrepresentation, false advertising, and breach of implied warranties of merchantability and fitness. SBC moved for summary judgment, contending that Lynnbrook's claims were preempted by APHIS regulations promulgated pursuant to the Virus-Serum-Toxin Act ("VSTA"), 21 U.S.C. §§ 151-159. APHIS declared that "states are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product." 57 Fed. Reg. 38759 (August 27, 1992). SBC maintained that this express declaration of preemption encompassed all of Lynnbrook's claims. Lynnbrook contested both the validity and the scope of the preemption provision. The district court agreed with SBC and granted summary judgment in its favor on all counts.

II.

We review the district court's grant of summary judgment *de novo. Green v. Shalala,* 51 F.3d 96, 99 (7th Cir. 1995). Summary judgment is appropriate where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(e). Even accepting the facts as recited above and giving Lynnbrook the benefit of all reasonable inferences (as we must in a summary judgment situation, *see Smith v. Shawnee Library Sys.,* 60 F.3d 317, 320 (7th Cir. 1995)), a finding that Lynnbrook's claims are preempted by federal law would entitle SBC to judgment as a matter of law.

At the outset, we note that the validity and scope of APHIS' preemption statement is one of first impression at

the circuit court level. According to our research, all other courts that have addressed the issue, including the district court below, have reached a conclusion similar to that which we reach today, i.e., that state common law claims of the type asserted in this case are preempted by the APHIS regulation. *See Lynnbrook Farms v. Smithkline Beecham Corp.*, 887 F. Supp. 1100 (C.D. Ill. 1995); *Murphy v. Smithkline Beecham Corp.*, 898 F. Supp. 811 (D. Kan. 1995); *Brandt v. The Marshall Animal Clinic and SmithKline Beecham Corp.*, 540 N.W.2d 870 (Minn. Ct. App. 1995).

A.

The Supremacy Clause of the Constitution declares that "the Laws of the United States . . . shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. The "Laws of the United States" encompasses both federal statutes and statutorily authorized federal agency regulations. *City of New York v. F.C.C.*, 486 U.S. 57, 63 (1988). With this understanding, the Supreme Court has delineated several avenues by which state law may be superseded by federal law, including when a federal agency acts within the scope of its congressionally delegated authority to preempt state law. *Id.* at 63-64; *Louisiana Public Service Comm'n v. F.C.C.*, 476 U.S. 355, 369 (1986); *Fidelity Federal Savings and Loan Assoc. v. De la Cuesta*, 458 U.S. 141, 152-54 (1982); *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699-700 (1984). "In proper circumstances, [an] agency may determine that its authority is exclusive and preempt[ ] any state efforts to regulate in the forbidden area." *City of New York*, 486 U.S. at 64. SBC claims that this type of preemption governs this

case. SBC's sole argument is that APHIS expressly preempted all state law claims pursuant to the power delegated to it under VSTA.[1]

In ascertaining whether an agency has acted properly in preempting state law, it is significant to note that an express Congressional authorization to displace state law in the delegating statute is unnecessary. *De la Cuesta*, 458 U.S. at 154. The Supreme Court has warned that a "narrow focus on Congress' intent to supersede state law [is] misdirected." *Id.*; *City of New York*, 486 U.S. at 64. Rather, the proper inquiry is to determine whether the power to preempt is within the bounds of authority granted to the agency by Congress, and if so, whether the agency has acted on this authority. *Id.* The Court has made it clear that the great deference generally afforded agency action is not discarded when the agency uses its delegated discretion to preempt. "Where Congress has directed an administrator to exercise his discretion," and the administrator promulgates regulations intended to preempt state law, "his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily." *De la Cuesta*, 458 U.S. at 154-55; *see also Crisp*, 467 U.S. at 699-700.

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[1] SBC is not claiming that APHIS' comprehensive agency regulation in the field implies preemptive intent on the part of Congress. *See Hillsborough County, Fla. v. Automated Medical Lab., Inc.*, 471 U.S. 707, 713 (1985) (extensive federal scheme of regulation may imply preemption). SBC is relying on APHIS' *express* preemption declaration, not a theory of *implied* preemption. Thus, Lynnbrook's arguments that APHIS' extensive regulations alone, without comprehensive regulation by Congress, cannot lead to implied preemption are inapposite.

Thus, we engage in a three-part analysis to determine if the regulatory actions of APHIS preempt Lynnbrook's state law claims. First, we must ascertain whether the power to preempt is within the authority delegated to the USDA and APHIS by Congress and is a rational exercise of that authority. If so, we then ask whether APHIS intended its regulations to preempt state common law claims. Finally, if APHIS did seek to preempt state common law, we consider whether the regulations preempt the specific causes of actions asserted by Lynnbrook.

B.

In order to answer the first question, we examine the congressional mandate that forms the basis of the agency's authority. VSTA requires that all animal vaccines produced in the United States and all establishments that manufacture such vaccines be licensed by the USDA. 21 U.S.C. § 154. The Act also broadly confers on the USDA the authority to "make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation [and] sale . . . of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals. . . . " *Id.* The USDA has delegated this responsibility and authority to APHIS. 9 C.F.R. § 101.2. APHIS, in turn, has promulgated an extensive regulatory scheme governing the design, manufacture, distribution, testing, and labelling of animal vaccines. *See* 9 C.F.R. §§ 101-24.

Prior to 1985, several courts held that the scope of VSTA, and hence the application of APHIS regulations,

was limited to products made and sold in interstate commerce. In other words, VSTA did not grant the USDA and APHIS the authority to regulate animal vaccines manufactured and sold within an individual state. *See Animal Health Institute v. U.S. Dept. of Agriculture*, 487 F. Supp. 376 (D. Colo. 1980); *Grand Lab., Inc. v. Harris*, 644 F.2d 729 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). In response, Congress amended VSTA in 1985 to clearly place both interstate and intrastate vaccines within the ambit of federal control. 21 U.S.C. § 151; S. Rep. No. 145, 99th Cong., 1st Sess. 338-39 (1985), *reprinted in* 1985 *U.S.C.C.A.N.* 1676, 2004-05. The amendments reflect the Congressional finding that federal regulation was "necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce." 21 U.S.C. § 159.

The legislative history supporting the VSTA amendments also evinces an unquestionable congressional intent to create national, uniform standards for the preparation and sale of animal vaccines. S. Rep. No. 145 at 339. Congress found that animal agriculture has "changed drastically" since the original 1913 passage of VSTA, including the development of "truly national markets." *Id.* It also noted that the industry recognized the need for national standards. *Id.* Congress thus concluded that uniform, federal standards would better serve livestock owners, veterinarians, and the American public. *Id.*

In reaction to the VSTA amendments, APHIS issued the declaration of preemption relied upon by SBC. The declaration states in relevant part:

> *[W]here safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field.* This includes, but is not

> limited to the regulation of labeling. Under VSTA, Congress clearly intended that there be national uniformity in the regulation of these products.
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> * * *
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> *APHIS . . . does not agree that States should be allowed to add various restrictions* . . . based upon a need to protect domestic animals or the public health, interests or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.
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> * * *
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> *States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States.* Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.

57 Fed. Reg. 38758, 38759 (August 27, 1992) (emphasis added).

We find that APHIS acted rationally and within the scope of the authority granted to it by Congress in issuing the above statement seeking to preempt state law. Congress granted the USDA and APHIS the broad regulatory power to promulgate and enforce "such rules and regulations as may be necessary" to prevent the production and sale of any "worthless, contaminated, dangerous

or harmful" animal vaccines. Congress also delegated to the USDA and APHIS the responsibility to eliminate "undue burdens" on commerce in this area, and toward that end, to establish a national, uniform regulatory scheme. It is apparent that APHIS' congressional mandate is to ensure safe and effective vaccines while at the same time minimize undue burdens on interstate commerce that often accompany varied state regulation. Given these powers and responsibilities, APHIS was acting rationally, and well within its congressionally delegated discretion, in creating a complex statutory scheme governing the safety, efficacy, purity, and potency of animal vaccines and in pronouncing this scheme to be the exclusive law in the area. The Supreme Court has held that:

> if the agency's choice to preempt "represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."

City of New York, 486 U.S. at 64 (quoting *United States v. Shimer*, 367 U.S. 374, 383 (1961)); *De la Cuesta*, 458 U.S. at 154. The instant case of preemption reflects a prime example of such an accommodation. Nothing in the legislative history of either VSTA or its amendments indicates that APHIS' actions would not be congressionally sanctioned. On the contrary, the course chosen serves only to further VSTA's purposes – further indicating that the agency was acting within its authority and not acting arbitrarily. *See De la Cuesta*, 458 U.S. at 159. Thus we

decline to disturb the agency's judgment to preempt state law.

Our conclusion is bolstered by several Supreme Court cases that have upheld agency decisions to preempt state law under similarly expansive congressional grants of authority. In *City of New York*, the Court upheld the FCC's power to preempt state and local cable television quality standards, citing the FCC's plenary authority to "[m]ake such rules and regulations and prescribe such restrictions and conditions . . . as may be necessary to carry out" the Commission's statutory purposes. 486 U.S. at 66-67; *see also Crisp*, 467 U.S. at 699-700. In support of its decision, the Court noted Congress' stated objectives to "establish a national policy concerning cable communications" and to "minimize unnecessary regulation that would impose an undue economic burden on cable systems." *City of New York*, 486 U.S. at 61 (quoting 47 U.S.C. §§ 521(1), (6) (1982)).

The Court similarly found that the Federal Home Loan Bank Board could preempt state common law restrictions on due-on-sale practices, as Congress authorized the Board "under such rules and regulations as it may prescribe, to provide for the organization, incorporation, examination, operation, and regulation" of federal savings and loan associations. *De la Cuesta*, 458 U.S. at 170 (quoting 12 U.S.C. § 146(a)(1)). The *De la Cuesta* Court found it significant that Congress' delegation placed no limits on the Board's authority to regulate the lending practices of federal savings and loans and included the power to create and regulate a "uniform system of [savings and loan] institutions where there are not any now." *Id.* at 161, 166. The grant of authority to the USDA and

APHIS under VSTA is no less broad than the power delegated to the FCC and the Federal Home Bank Loan Board. And like those agencies, APHIS has been charged with establishing a uniform, national regulatory scheme.

Lynnbrook apparently acknowledges that Congress granted APHIS the authority to preempt state *regulations* concerning animal vaccines, yet questions APHIS' power to preempt state *tort actions*. Lynnbrook argues that this power is lacking based on the absence of any express authority to preempt state tort law in VSTA. However, as we have already noted, a specific congressional authorization is not a prerequisite to the validity of an agency's preemption decision. The Court has clearly stated that "[f]ederal regulations have no less preemptive effect than federal statutes. . . . A preemptive regulation's force does not depend on express congressional authorization to displace state law. . . . " *De la Cuesta,* 458 U.S. at 153-54.

Lynnbrook also relies on prior caselaw preserving state tort claims in the area of human vaccines to argue that APHIS' delegated authority is limited to preemption of positive regulations. These cases are all distinguishable in important respects. Several of the cases invoked the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-1 *et seq.*) and the Vaccine Compensation Amendments (26 U.S.C. § 9510) in finding no preemption of state tort claims.[2] However, in these acts Congress explicitly

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[2] *Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir.), *cert. denied*, 488 U.S. 908 (1988); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483 (D. Kan. 1987), and *Foyle v. Lederle Lab.*, 674 F. Supp. 530 (E.D.N.C. 1987).

preserved state tort claims for human vaccine related injuries. *See Abbot*, 844 F.2d at 1109 (4th Cir. 1988). The remaining cases cited by Lynnbrook involved FDA regulations;[3] yet the FDA has never expressed any intent to preempt state tort law. On the contrary, the FDA has expressly preserved state tort labelling claims. *Bansemer*, 1990 WL 132579 at *3. Thus, these cases do not persuade us that there is a congressionally intended distinction in VSTA between the power to preempt state regulations and the power to preempt state tort claims.

Lynnbrook finally invokes the presumption against preemption and the heightened presumption in areas that have traditionally been the province of the states, such as health and safety. *Abbot*, 844 F.2d at 1112. This presumption, however, can be overcome by an agency's clear declaration of intent to preempt state law. *Hillsborough County, Fla. v. Automated Medical Lab., Inc.*, 471 U.S. 707, 715-16 (1985) (noting that presumption governs unless preemption "was the clear and manifest purpose of Congress. . . . Of course, the same principles apply where, as here, the field is said to have been preempted by an agency. . . . "). Thus, if APHIS' declaration of preemption clearly encompasses state tort claims (which is our next inquiry), the presumption against preemption offers Lynnbrook no shelter.

We further note that, where similarly broad grants of authority have been involved, the Supreme Court has

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[3] *Bansemer v. Smith Lab., Inc.*, 1990 WL 132579 (E.D. Wis. 1988); *Hoppe v. G.D. Searle & Co.*, 779 F. Supp. 1413 (S.D.N.Y. 1991); *Ferrigno v. Eli Lilly & Co.*, 420 A.2d 1305 (N.J. Super. Ct. 1980); and *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973).

never intimated a distinction between agency authority to preempt state law generally and the authority to preempt state common law. *See De la Cuesta*, 458 U.S. at 152-67; *Crisp*, 467 U.S. at 698-705; *City of New York*, 486 U.S. at 63-69. On the contrary, the *De la Cuesta* Court, without hesitation, upheld agency preemption of a state common law rule – a state regulation or statute was not involved. 458 U.S at 148-49.

Moreover, it is significant that in this case Congress was concerned with establishing national uniform standards for animal vaccines. The Supreme Court has recognized that state tort law can impose standards in a manner similar to positive enactments. *See Cipollone v. Liggett Group*, 112 S. Ct. 2608, 2620 (1992) ("state regulation can be as effectively exerted through an award of damages as through some form of preventive relief"). State tort actions can therefore be as much of a threat to national uniformity as affirmative state regulation. Thus, without any congressional indication to the contrary, it follows that Congress included within its grant of preemption power, the power to preempt state common law. Lynnbrook's argument in this case essentially creates a distinction without a meaningful difference. In sum, we are confident that if APHIS intended to preempt state common law, it was acting within its congressionally delegated authority.

C.

As set forth above, APHIS' preemption statement is clear and comprehensive. In an effort to fulfill its mandate to create a national, uniform system of regulations,

APHIS announced it intended to "occupy the field" concerning "the safety, efficacy, purity and potency of biological products." Toward this goal, APHIS decisively stated that "[s]tates are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product." Lynnbrook argues that this statement reflects only an intent to preempt state regulation of animal vaccines or similar positive enactments, but not an intent to preempt state common law actions such as those brought by Lynnbrook. We are not persuaded.

First, APHIS chose language that mirrors preemption language in federal statutes that has been held by the Supreme Court, this court, and many other courts, to preempt both state regulations and common law damages actions. In *Cipollone v. Liggett Group*, 112 S. Ct. 2608 (1992), the Supreme Court interpreted the preemption provision in the Public Health Cigarette Smoking Act of 1969, which amended the earlier Federal Cigarette Labeling and Advertising Act of 1965. The 1969 provision provided:

> *No requirement or prohibition* based on smoking and health shall be imposed under state law with respect to the advertising and promotion of any cigarettes the packages of which are labelled in conformity with the provision of this Act.

Id. at 2617.[4] The petitioners in *Cipollone* made the same argument that Lynnbrook advances here, maintaining

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[4] The Court also interpreted the original preemption provision in the 1965 Act. That provision stated:

> (a) No statement relating to smoking and health, other than the statement required by section 4 of this

that the provision was not intended to preempt state common law causes of action. The Court disagreed, finding "such an analysis [ ] at odds with the plain words of the 1969 Act and with the general understanding of common law damages actions." *Id.* at 2620. The Court continued: "The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." The Court thus rejected the petitioner's argument and held that the provision preempted common law actions. *Id.* at 2621. The Court warned, however, that the clause should not be taken as a blanket preemption of all common law claims. *Id.* The Court continued its analysis to determine which claims fell under the specific language of the clause. *Id.*

Following the Supreme Court's lead, we and other circuit courts (as well as many district courts) have held that language similar to that in *Cipollone*, and substantially the same as the APHIS preemption provision, encompasses common law actions. For instance, in *Shaw v. Dow Brands, Inc.*, 994 F.2d 364 (7th Cir. 1993), we were called upon to determine the scope of the preemption

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Act, shall be required on any cigarette package.

(b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

Cipollone, 112 S. Ct. at 2616. Finding this language much more narrow and precise than the language in the 1969 provision, the Court held the prior language was not intended to preempt state tort laws. *Id.* at 2619.

language in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b). The act stated that "[s]uch State shall not impose . . . any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Id.* at 370. With *Cipollone* as our touchstone, we found that the *Cipollone* language of "[n]o requirements or prohibitions" was "just another way of saying a [s]tate shall not impose . . . any requirements," and we therefore held that plaintiff's strict liability and negligence failure to warn claims were preempted by FIFRA. *Id.* at 371. Six other circuits have reached similar conclusions. *See, e.g., Taylor AG Industries v. Pure-Gro,* 54 F.3d 555 (9th Cir. 1995); *Bice v. Leslie's Poolmart,* 39 F.3d 887 (8th Cir. 1994); *MacDonald v. Monsanto Co.,* 27 F.3d 1021 (5th Cir. 1994); *Worm v. American Cyanamid Co.,* 5 F.3d 744 (4th Cir. 1993); *King v. E.I. DuPont De Nemours & Co.,* 996 F.2d 1346 (1st Cir.), *cert. dismissed,* 114 S. Ct. 490 (1993); *Papas v. Upjohn Co.,* 985 F.2d 516 (11th Cir.), *cert. denied,* 114 S. Ct. 300 (1993). More recently, we have held that language in the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), proscribing "any requirement . . . different from, or in addition to," those established pursuant to the MDA extended to preempt certain common law actions. *Mitchell v. Collagen Corp.,* 67 F.3d 1268, 1276 (7th Cir. 1995); *see also Slater v. Optical Radiation Corp.,* 961 F.2d 1330, 1333 (7th Cir.), *cert. denied,* 506 U.S. 917 (1992). Many circuits agree. *See, e.g., Michael v. Shiley, Inc.,* 46 F.3d 1316 (3rd Cir.), *cert. denied,* 116 S. Ct. 67 (1995); *Reeves v. AcroMed Corp.,* 44 F.3d 300 (5th Cir.),

cert. denied, 115 S. Ct. 2251 (1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994).[5] Lynnbrook has not distinguished the language used by APHIS in any meaningful way from the language used in FIFRA or the MDA.[6] In the face of this strong and consistent authority, we are compelled to reach the same conclusion we reached in *Shaw*. If common law actions cannot survive under the 1969 cigarette law, FIFRA or the MDA, then common law actions imposing additional requirements on animal vaccines cannot survive the reach of the APHIS provision. *See Shaw*, 994 F.2d at 371.

Although the caselaw supporting our conclusion is substantial, we are even more confident that APHIS intended to include common law damages actions within the scope of its preemption after reviewing the only official APHIS statement (to our knowledge) explaining its intent in adopting the quoted regulation. In a letter dated December 22, 1995, the Acting Administrator of the agency explained, that the intent in "promulgating the rule was, and continues to be, to preempt States from

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[5] Similar language in the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1261, has also been held to preempt common law damages actions. *See Moss v. Parks Corp.*, 985 F.2d 736 (4th Cir.), *cert. denied*, 113 S. Ct. 2999 (1993).

[6] Lynnbrook's only attempt to avoid the result dictated by these precedents is to claim that, in the cases of FIFRA and the MDA, the language was employed by Congress in a statute, not by an agency in a regulation. However, as we have now noted several times, this is of no moment, as "federal regulations have no less preemptive effect than federal statutes." *De la Cuesta*, 458 U.S. at 153-54.

imposing requirements either through statutes, regulations, *or other means* that are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product." (emphasis added).[7] The letter further stated that "[w]e did not intend to preempt common law actions for damages *arising from noncompliance with USDA regulatory standards.*" (emphasis added). Interestingly, both sides claim the letter unequivocally supports their position.

We must agree with SBC that the correspondence confirms the interpretation that APHIS intended certain state tort claims to be preempted. Contrary to Lynnbrook's argument that APHIS only intended to preempt positive enactments, the agency included in its preemptive scope additional requirements dictated by States via "regulations, statutes, or other means." The phrase "or other means" clearly encompasses state tort claims. Moreover, APHIS' letter signals that state tort claims are available when APHIS regulatory standards are violated or disregarded. The natural conclusion to draw from this statement is that when APHIS regulations are heeded, state tort claims involving the safety, efficacy, potency, or purity of an animal vaccine do *not* survive. This dichotomy follows from the preemption language chosen by APHIS, as it is precisely when APHIS regulations have

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[7] Following oral argument, Lynnbrook submitted a motion to take judicial notice of the letter from APHIS, along with two other letters. The motion is granted as to the December 22, 1995 APHIS letter; the motion is denied as to the other two letters. The parties have also made several other post oral argument motions, all of which we deny.

been satisfied that a common law action imposes requirements in addition to, or different from, those mandated by APHIS.[8] Where noncompliance is involved, a common law action could simply serve to impose the standards of APHIS. Thus, it is evident that APHIS intended to preempt common law claims relating to areas under its regulatory control (namely the safety, purity, potency, and efficacy of vaccines) which would impose additional or different requirements on vaccines, i.e., common law claims involving regulated areas in cases where the manufacturer has complied with all APHIS regulations and standards. The last step is to determine if Lynnbrook's claims fall within this preempted group of claims.

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[8] APHIS regulations extensively govern the manufacture and marketing of vaccines in order to ensure their safety, purity, potency and efficacy. For instance, manufacturers are required to submit an "Outline of Production" detailing every step in the design, testing, production, and packaging of all animal vaccines. *See* 9 C.F.R. §§ 114.8-9. The outline is a precondition to licensure by APHIS, and no changes may be made to the outline without approval from APHIS. 9 C.F.R. § 102.5(d)(1). In addition, the regulations provide an elaborate testing protocol that must be administered by the manufacturer or by APHIS. *See* 9 C.F.R. §§ 113.25-55; 9 C.F.R. §§ 113.64-.332. Further, APHIS requires all animal vaccines to list certain information on all labels, including the container label, the carton label, and any product insert, circular or leaflet. 9 C.F.R. § 112. The label must be approved by APHIS in writing prior to licensure. *Id.* Thus, when all regulations are complied with and APHIS licenses the vaccine, it is clear that the vaccine satisfies APHIS standards for safety, purity, potency, and efficacy.

D.

It is undisputed that SBC manufactured and marketed Cattlemaster 4 and Ultrabac 7/Somubac according to all APHIS regulations. This is not a case involving noncompliance. Both vaccines have met APHIS standards for safety, purity, potency, and efficacy. Thus, if Lynnbrook's claims relate to these qualities, seeking to impose additional or different requirements in these areas, they are preempted. We find that this describes all of Lynnbrook's claims.

Counts I and VII of Lynnbrook's complaint sound in strict products liability (one for each vaccine), apparently based on the theory that the vaccines were defective and unreasonably dangerous. If these claims are allowed to proceed they would impose a duty on SBC regarding at least the safety (if not also the efficacy, purity and potency) of the cattle vaccines different from the requirements enforced by APHIS. Counts II and III state claims for breach of implied warranties of fitness for a particular purpose and of merchantability. These actions clearly implicate the efficacy and safety of the vaccines and would likewise impose higher or different standards on SBC.

Counts IV and V of the complaint allege fraudulent misrepresentation and false advertising under the common law and the Illinois Consumer Fraud and Deceptive Business Practices Act. Lynnbrook alleges that SBC falsely represented that the vaccines were safe and effective when it knew they were not. In order to succeed on these claims, a jury would have to find that the vaccines were not safe and effective. However, APHIS has already

declared the products safe and efficacious by its standards. Thus a different standard would be enforced. In addition, these counts could be viewed as failure to warn claims, *see King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993), which would result in labeling requirements distinct from those dictated by APHIS. The same is true of Counts VI and VIII, which allege strict liability failure to warn claims (one for each vaccine).

APHIS has licensed both Cattlemaster 4 and Ultrabac 7/Somubac and thus declared the vaccines are safe, efficacious, potent and pure by its measures. By bringing claims that clearly implicate and call into question these qualities, Lynnbrook seeks to "impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency or purity of a product." The claims are thus preempted in their entirety.

III.

We recognize that the conclusion we reach today leaves Lynnbrook and similar plaintiffs no remedy for the injuries and losses that they have suffered. However, we are not at liberty to reverse the judgments of an agency acting within its congressionally delegated authority. It is evident not only that APHIS intended claims such as those brought by Lynnbrook to be preempted, but also that Congress granted APHIS the power to act on those intentions. Therefore we AFFIRM the district court's order granting summary judgment in SBC's favor.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS

LYNNBROOK FARMS, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION and NORDEN LABORATORIES, Defendants.	)	Case No. 94-1227

ORDER

(Filed Mar. 30, 1995)

This matter comes before the Court on Defendants' Motion to Dismiss [7] and Motion for Summary Judgment [15]. Pursuant to Local Rule 1.4, the Motion to Dismiss was referred to Magistrate Judge Robert J. Kauffman. While reviewing the motion, Magistrate Kauffman determined that due to the existence of the affirmative defense of federal preemption, the Motion to Dismiss should not be ruled upon until the parties had briefed the preemption issue. (Order dated October 12, 1994). The Defendants subsequently filed their Motion for Summary Judgment, which relies solely on the issue of federal preemption in support of the motion. This Court heard oral argument on the motion on February 24, 1995 and gave the parties leave to file proposed findings of fact and conclusions of law. (Transcript of 2/24/95 hrg. at 22-23). Defendants timely filed their Proposed Findings

of Fact and Conclusions of Law [23]. Plaintiff has apparently elected not to file a proposed pleading. The Court has reviewed the pleadings, affidavits and other materials submitted to the Court in support of and in opposition to the Motion for Summary Judgment and, for the reasons set forth herein, GRANTS the Motion for Summary Judgment [15] and finds the Motion to Dismiss DENIED [7] as moot.

Findings of Fact

Plaintiff, Lynnbrook Farms, is a general partnership organized under the laws of Illinois. (Amended Complaint at 1). Defendant Norden Laboratories merged into Smithkline Beacham on or about January 1, 1992. (Answer to Amended Complaint at 3). Prior to the merger, Norden Laboratories existed as a Delaware corporation. (Amended Complaint at 2). Defendant Smithkline Beecham is a corporation organized under the laws of Pennsylvania. *Id.* at 1-2. The Defendants will hereafter be referred to as "SBC." The parties have stipulated that the amount in controversy is in excess of $50,000. (Answer to Amended Complaint at 2). This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

The Amended Complaint, filed June 6, 1994, alleges that Defendants manufacture animal vaccines for ultimate sale to the public in the State of Illinois. (Amended Complaint at 3). Defendants deny that their animal vaccines were sold to various firms for distribution to the public, answering instead that the "vaccines in question were subject to use, evaluation and administration by

veterinary physicians under the learned intermediary doctrine." (Answer to Amended Complaint at 4).

The vaccines at issue in this suit are *CattleMaster4 and Ultrabac7/Somubac. (Amended Complaint at 3, 11). The United States Department of Agriculture ("USDA") has licensed each of the vaccines, *CattleMaster4 under USDA License No. 1187.21 and Ultrabac7/Somubac under USDA License No. 4723.00. (Affidavit of Cyril G. Gay, D.V.M., Ph.D. at ¶¶ 3-9). Plaintiff contends that it purchased these vaccines from the Miller Company in Morton, Illinois. (Amended Complaint at 3, 11). According to the Amended Complaint, Plaintiff intended to use these vaccines on its cattle to prevent debilitating disease and/or mortal infection. *Id.* at 3, 12. Plaintiff alleges that notwithstanding its use of the vaccines, some of its cattle contracted debilitating disease and died. *Id.* at 4, 12-13. Other cattle had to be disposed of at a loss due to the extent of debilitations. *Id.* The Amended Complaint asserts that Plaintiff took all recommended precautions, including refrigerating the vaccines, and despite these actions the vaccines did not perform as they were intended. *Id.* at 4, 12. Plaintiff further asserts that these vaccines proximately caused the debilitation and death of its cattle. *Id.*

The Amended Complaint presents eight counts. In Counts I and VII, Plaintiff asserts that SBC is liable, under a strict liability theory, for the defective, dangerous, and inefficacious nature of *CattleMaster 4 and Ultrabac7/Somubac, respectively. Counts II and III contain allegations that SBC breached implied warranties of fitness for a particular purpose and merchantability under the Illinois Uniform Commercial Code, 810 ILCS 5/1-101, *et seq.*

Count IV states a claim for fraudulent misrepresentation. Count V alleges that SBC violated the Illinois Consumer Fraud and Deceptive Practices Act, 815 ILCS 505/1, *et seq.*, through the advertising and promotion of *CattleMaster4. In Counts VI and VII, Plaintiff contends that the *CattleMaster4 and Somubac vaccines were defective in that the product labeling on the vaccines failed to warn against certain alleged dangers arising out of their use.

Conclusions of Law

Summary judgment will be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). Once the moving party has borne its burden of identifying those portions of the pleadings, answers to interrogatories, etc., that demonstrate there is no genuine issue of material fact, the nonmoving party must come forward with specific facts showing that there is a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87, 106 S.Ct. 1348, 1356 (1986). Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial. *Id.* at 587 (citations omitted). When considering a motion for summary judgment, courts must give the benefit of all inferences to the party opposing the motion and examine the record in the light most favorable to that party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655, 82 S.Ct. 993, 994 (1962); *Sarsha v. Sears, Roebuck & Co.*, 3 F.3d 1035, 1038 (7th Cir. 1993).

In this matter, the Court gives the benefit of all inferences to the Plaintiff, for purposes of the Motion for Summary Judgment, regarding Plaintiff's allegations that it purchased the vaccines, *CattleMaster4 and Ultrabac7/ Somubac, for use on its cattle; that it properly utilized these vaccines; and that its cattle contracted debilitating disease and either died or had to be disposed of at a loss. All this being true, however, will not permit the Plaintiff to survive summary judgment if the Virus-Serum-Toxins Act ("VSTA") preempts Plaintiff's state common law and statutory claims.[1] In the event that this Court finds VSTA to preempt state law, Plaintiff, for all the injury sustained by it, will have no remedy at law.

The presumption against preemption, especially where the state law being usurped is a traditional state police power, is well established. *California v. ARC America Corp.*, 490 U.S. 93, 100, 109 S.Ct. 1661, 1665 (1989); *Maryland v. Louisiana*, 451 U.S. 725, 746, 101 S.Ct. 2114, 2129 (1981) ("Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law"); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152 (1947) ("we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress") (citations omitted). The same presumption

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[1] All animal vaccines marketed in the United States are regulated by the USDA pursuant to authority delegated to it by Congress under VSTA. 21 U.S.C. §§ 151-158. USDA's Animal and Plant Health Inspection Service ("APHIS") is responsible for administering VSTA. 9 C.F.R. § 101.2; *Foundation on Economic Trends v. Lyng*, 680 F.Supp. 10, 11 (D.D.C. 1988).

applies when an agency acts to preempt the field. *Hillsborough County, Fla. v. Automated Medical laboratories, Inc.*, 471 U.S. 707, 715, 105 S.Ct. 2371, 2376 (1985). In instances where agency preemption is alleged, however, a "narrow focus on Congress' intent to supersede state law [is] misdirected," as "[a] preemptive regulation's force does not depend on express congressional authority to displace state law." *Fidelity Federal Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154, 102 S.Ct. 3014 (1982).

Congress may act to preempt state law in three ways. Express preemption exists where Congress has legislated in clear and unequivocal terms, found within the text of the statute, that an act preempts state law. *See, e.g., Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2617-20 (1992). Implied preemption may be found (1) where state law actually conflicts with an act of Congress, or (2) where federal legislation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it. *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 404 (1941). Finally, state law may be preempted by federal regulations, *Hillsborough, supra*, at 713, where a federal agency, acting within the scope of its congressionally delegated authority, acts to preempt state law. *Fidelity Federal Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54, 102 S.Ct. 3014, 3022-23 (1982) (citations omitted); *City of New York v. F.C.C.*, 486 U.S. 57, 63-64, 108 S.Ct. 1637, 1642 (1988) (citing *Louisiana Public Service Com'n v. F.C.C.*, 476 U.S. 355, 106 S.Ct. 1890, 1898-99 (1986)).[2]

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[2] The regulations of a federal agency will preempt state or local laws which conflict with or frustrate the purposes of the regulations. *City of New York, supra*, at 64. In certain situations,

In the case at bar, Defendants have eschewed the express and implied preemption arguments, relying solely upon agency preemption to support its Motion for Summary Judgment. (Tr. of 2/24/95 Oral Argument at 3-4). Thus, this Court must determine first whether the agency which regulated cattle vaccines, APHIS, was acting within its congressionally delegated authority. *City of New York, supra,* at 63-64. Once this Court finds that APHIS was acting within its grant of authority, it must determine whether the language APHIS chose in promulgating its regulations is sufficiently broad to preempt each of Plaintiff's claims. *Id.* at 66.

Under VSTA, all animal vaccines sold in the United States, and all establishments at which animal vaccines are produced, must be licensed by the USDA. 21 U.S.C. § 154 (West Supp. 1994). Within USDA, licensure of animal vaccines and vaccine-producing establishments is regulated by the USDA's APHIS. 9 C.F.R. § 101.1, *et seq.* This Court finds that Congress has delegated broad authority to the USDA and APHIS to promulgate and enforce "such rules and regulations as may be necessary" for the preparation and sale of animal vaccines in the United States. 21 U.S.C. § 154 (West Supp. 1994).

In 1980 and 1981, several federal court opinions issued which found that the breadth of VSTA was limited to "interstate" commerce. *See Animal Health Institute v. U.S. Dept. of Agriculture,* 487 F.Supp. 376 (D.Colo. 1980); *Grand Laboratories, Inc. v. Harris,* 644 F.2d 729 (8th Cir.

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the agency may declare its authority exclusive, which then requires finding any state or local effort to regulate within the area preempted. *Id.*

1981), *on rehearing*, 660 F.2d 1288 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). These decisions found that the USDA did not have the authority to regulate the production and sale of products made within a single state. *Animal Health Institute*, 487 F.Supp. at 379; *Grand Laboratories*, 644 F.2d at 731, 660 F.2d at 1289. Congress responded to these cases by amending VSTA to eliminate any distinction between "intrastate" and "interstate" manufacture and distribution of animal vaccines. S.Rep.No. 99-145, 99th Cong., 1st Sess. at 338-9 (1985), *reprinted in* 1985 *U.S. Code Congressional & Administrative News*, 1676, 2004-5. This congressional action placed the manufacture and sale of all animal vaccines under the control of the United States federal government. 21 U.S.C. § 151.

The legislative history surrounding the 1985 amendments to VSTA indicates Congress' intent to create a national, uniform standard for the preparation and sale of animal vaccines. S.Rep.No. 99-145. In this excerpt of legislative history, Congress noted that an "intrastate/interstate" distinction no longer exists for comparable products such as animal drugs, food additives, medical devices, or pesticides. *Id.* Congress concluded that due to the drastic changes in animal agriculture since 1913, including the presence of "truly national markets," a uniform regulatory standard would better serve "livestock owners, veterinarians, and the American public." *Id.*

As a basic for comparison, this Court studied the decision in *City of New York*, in which the Supreme Court decided whether the Federal Communications Commission ("FCC") had properly acted within its congressionally delegated power in preempting state and local cable

television quality standards. 486 U.S. at 66. The Court turned to both the Cable Communications Policy Act of 1984, 47 U.S.C. §§ 521-559 (1982 ed., Supp. IV), and the Communications Act of 1934 to analyze the breadth of power the FCC had been granted by Congress. *Id.* at 60-62. In an earlier decision, *Capital Cities Cable, Inc. v. Crisp*, the Court had found that Congress authorized the FCC "to regulate all aspects of interstate communication by wire or radio." 467 U.S. 691, 700, 104 S.Ct. 2694 (1984). According to the *Crisp* Court, this authority extended to "all regulatory actions 'necessary to ensure the achievement of the Commission's statutory responsibilities.' " *Id.* (quoting *F.C.C. v. Midwest Video Corp.*, 440 U.S. 689, 706, 99 S.Ct. 1435, 1444 (1979)). Shortly after the *Crisp* decision, Congress enacted the 1984 Cable Act, which states that Congress intended to "establish a national policy concerning cable communications" and to "minimize unnecessary regulation that would impose an undue economic burden on cable systems." 47 U.S.C. §§ 521(1), (6) (1982 ed., Supp IV).

The language in the 1985 amendments to VSTA are no less broad than the grant of authority to the FCC in the 1934 and 1984 Acts. The language Congress chose in enacting the 1985 amendments to VSTA indicates its intent to grant the USDA broad powers "necessary to prevent and eliminate burdens on . . . commerce and to effectively regulate . . . commerce." 21 U.S.C. § 159. Congress gave the Secretary of Agriculture the power to "make and promulgate from time to time such rules and

regulations as may be necessary to prevent the preparation, sale . . . or shipment . . . of any worthless, contaminated, dangerous or harmful virus, serum, toxin, or analogous product. . . . " 21 U.S.C. § 154.

Having found that the congressional grant of power to USDA's APHIS was broad enough to include the authority to preempt state laws, this Court must now turn to the second prong of this analysis, which is whether the language that APHIS chose in promulgating its regulations is sufficiently broad to preempt each of Plaintiff's claims. *De la Cuesta, supra,* at 153-54. "[W]here Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial review only to determine whether he has exceeded his statutory authority or acted arbitrarily." *Id.*

SBC asserts that APHIS has expressly construed the 1985 amendments to VSTA as reserving to the federal government the exclusive responsibility for the safety, efficacy, purity, potency, and labeling of animal vaccines. Further, SBC seeks to invoke the rule that unless an agency's decision to preempt state law is arbitrary or capricious, "it must be given controlling weight by the reviewing court." *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 845, 104 S.Ct. 2778 (1984).

In the August 27, 1992 Federal Register, APHIS articulated its interpretation of the 1985 amendments, in relevant part, as follows:

> Where safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field. This

> includes, but is not limited to the regulation of labeling. Under [the 1985 amendments to VSTA], Congress clearly intended that there be national uniformity in the regulation of these products.
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> * * *
>
> APHIS . . . does not agree that States should be allowed to add various restrictions . . . based upon a need to protect domestic animals or the public health, interests or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.
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> * * *
>
> [S]tates are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent and efficacious.

57 *Fed. Reg.* 38758, 38759 (August 27, 1992).

The Court must turn to the analysis set out in *Chevron* to determine whether or not this interpretation of the 1985 amendments is to be given controlling weight. 467 U.S. 837, 842-43. As Congress has not directly spoken to the issue of preemption, the Court must decide whether

APHIS' declaration of preemption is based upon a permissible construction of VSTA. *Chevron*, 467 U.S. at 843-44. APHIS' interpretation can be found to be based upon a permissible construction, thus entitled to controlling weight, if it is not arbitrary, capricious or manifestly contrary to VSTA.[3] *Id.*

The language of the amendments, including those sections aforementioned which grant the Secretary of Agriculture the authority to "make and promulgate such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange or shipment . . . of any worthless contaminated, dangerous or harmful . . . serum, toxin, or analogous product," 21 U.S.C. § 154, "to prevent and eliminate burdens on [interstate] commerce and to effectively regulate such commerce," 21 U.S.C. § 159, allow the permissible interpretation that APHIS may preempt state law. The choice to preempt state law represents "a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute," *United States v. Shimer*, 367 U.S. 374, 382, 81 S.Ct. 1554 (1961), in that it would be difficult to prevent or eliminate burdens on interstate commerce if each of the 50 states could impose different regulations on animal vaccines. Thus, APHIS' reading is neither arbitrary nor capricious.

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[3] The Supreme Court held in *Morton v. Ruiz*, 415 U.S. 199, 231, 94 S.Ct. 1055, 1072 (1974), that "[t]he power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress."

Further, it is congruous with VSTA's purpose of regulating the safety, efficacy, purity, potency, and labeling of animal vaccines.

Finally, the Court must analyze the various claims of Plaintiff to determine whether the legal duty that is the predicate of the common law damages counts, *Cipollone, supra,* at 2621, would impose a requirement upon the Defendants which is "different from, or in addition to, those imposed by the USDA regarding the safety, efficacy, potency, or purity of a product." *Cipollone, supra,* at 2621; 57 *Fed. Reg.* 38758, 38759 (August 27, 1992).

It is noteworthy that several Courts of Appeal, including the Seventh Circuit, have previously addressed language similar to that of APHIS' regulations in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136, *et seq.* Section 136v(b) of FIFRA, entitled Authority of the States, provides as follows:

> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required by this subchapter.

7 U.S.C. § 136v.

The majority of circuits to consider FIFRA's preemptive reach, including the Seventh Circuit, find this language to preempt both positive enactments and common law. *MacDonald v. Monsanto Co.,* 27 F.3d 1021 (5th Cir. 1994); *Bice v. Leslie's Poolmart, Inc.,* 39 F.3d 887 (8th Cir. 1994); *King v. E.I. Dupont De Nemours and Co.,* 996 F.2d 1346 (1st Cir. 1993), *cert. dismissed,* 114 S.Ct. 490 (1993); *Worm v. American Cyanamid Co.,* 5 F.3d 744 (4th Cir. 1993);

Shaw v. Dow Brands, Inc., 994 F.2d 364 (7th Cir. 1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir. 1993), *cert. denied*, 114 S.Ct. 60 (1993); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993), *cert. denied* by *Papas v. Zoecon Corp.*, 114 S.Ct. 300 (1993).

Applying this logic, Counts I and VII of Plaintiff's Amended Complaint, which allege the two vaccines were defective, dangerous, and inefficacious, would impose a duty on SBC regarding the safety, efficacy, potency, or purity of the cattle vaccines which would be in addition to or different from those regulations promulgated by the USDA and enforced by APHIS.

Similarly, Counts II and III allege that SBC breached implied warranties of fitness of a particular purpose and merchantability, respectively. These allegations implicate the safety and efficacy of SBC's cattle vaccines and, as such, are preempted by VSTA.

Counts IV and V state claims for fraudulent misrepresentation and false advertising, alleging that Defendants knew the vaccine *CattleMaster4 was dangerous and lacked efficacy. These claims are inherently failure to warn claims which, if not preempted, would allow a jury to determine that the vaccine was unsafe and/or inefficacious. Thus, a requirement different from or in addition to those set out by APHIS would be imposed upon SBC. These Counts are both preempted.

With regard to the failure to warn claims, Counts VI and VIII, APHIS has expressly stated that "labeling requirements which are different from or in addition to those in the regulations under the Act may not be

imposed by the States." 57 *Fed. Reg.* at 38759. Thus, to the extent that Plaintiff's failure to warn claims would require SBC to alter the labels of its cattle vaccines, they are also preempted.

All this being said, the Court is troubled by the absence of a federal remedy. Based on the breadth of APHIS' congressional grant of authority, the express language of the regulations, and the agency's permissible interpretation of VSTA, however, this Court can come to no other viable conclusion.

Conclusion

For the reasons set forth herein, the Court GRANTS the Defendants' Motion for Summary Judgment in favor of Defendants Smithkline Beecham and Norden Laboratories and against Plaintiff. Lynnbrook Farms, and finds the Motion to Dismiss DENIED as moot.

ENTERED this 30th day of March, 1995.

/s/ Michael M. Mihm
Michael M. Mihm
Chief United States
District Judge

APPENDIX C

United States Court of Appeals
For the Seventh Circuit
Chicago, Illinois 60604

April 22, 1996

HON. JOEL M. FLAUM, Circuit Judge

HON. ILANA D. ROVNER, Circuit Judge

HON. TERENCE T. EVANS, Circuit Judge

LYNNBROOK FARMS, an Illinois General Partnership, Plaintiff-Appellant, No. 95-2051 v. SMITHKLINE BEECHAM CORPORATION, Defendant-Appellee.	] Appeal from the United States District Court for the Central District of Illinois, Peoria Division. No. 94 C 1227 Michael M. Mihm, Chief Judge.

ORDER

On consideration of the petition for rehearing and suggestion for rehearing *en banc* filed in the above-entitled cause on April 3, 1996, by plaintiff-appellant, no judge in active service has requested a vote thereon, and all of the judges on the original panel have voted to deny a rehearing. Accordingly,

IT IS ORDERED that the aforesaid petition for rehearing and suggestion for rehearing *en banc* be, and the same is hereby **DENIED.**

APPENDIX D

CHAPTER 5 – VIRUSES, SERUMS, TOXINS, ANTITOXINS AND ANALOGOUS PRODUCTS

21 U.S.C. § 151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

(As amended Dec. 23, 1985, Pub.L. 99-198, Title XVII, § 1768(a), 99 Stat. 1654.)

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21 U.S.C. § 152. Importation regulated and prohibited

The importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without (1) a permit from the Secretary of Agriculture, or (2) in the case of an article originating in Canada, such permit or, in lieu of such permit, such certification by Canada as may be prescribed by the Secretary of Agriculture.

(As amended Sept. 28, 1988, Pub.L. 100-449, Title III, § 301(d), 102 Stat. 1868.)

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21 U.S.C. § 153. Inspection of imports; denial of entry and destruction

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21 U.S.C. § 154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is hereby authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals or otherwise to carry out

this paragraph, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid.

(As amended Dec. 23, 1985, Pub.L. 99-198, Title XVII, § 1768(b), 99 Stat. 1654.)

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21 U.S.C. § 154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria

In order to meet an emergency condition, limited market or local situation, or other special circumstance (including production solely for intrastate use under a State-operated program), the Secretary may issue a special license under an expedited procedure on such conditions as are necessary to assure purity, safety, and a reasonable expectation of efficacy. The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation –

(1) solely for administration to animals of such person, firm, or corporation;

(2) solely for administration to animals under a veterinarian-client-patient relationship in the course of the State licensed professional

practice of veterinary medicine by such person, firm, or corporation; or

(3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet criteria under which the State –

(A) may license virus, serum, toxin, and analogous products and establishments that produce such products;

(B) may review the purity, safety, potency, and efficacy of such products prior to licensure;

(C) may review product test results to assure compliance with applicable standards for purity, safety, and potency, prior to release to the market;

(D) may deal effectively with violations of State law regulating virus, serum, toxin, and analogous products; and

(E) exercises the authority referred to in subclauses (A) through (D) consistent with the intent of this paragraph of prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products.

(Pub.L. 99-198, Title XVII, § 1768(c), Dec. 23, 1985, 99 Stat. 1654.)

21 U.S.C. § 155. Permits for importation

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21 U.S.C. § 156. Licenses conditioned on permitting inspection; suspension of licenses

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21 U.S.C. § 157. Same; inspection daytime or nighttime

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

(As amended Dec. 23, 1985, Pub.L. 99-198, Title XVII, § 1768(d), 99 Stat. 1655.)

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21 U.S.C. § 158. Offenses; punishment

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21 U.S.C. § 159. Enforcement; penalties applicable Congressional findings

The procedures of sections 672, 673, and 674 of this title (relating to detentions, seizures and condemnations, and injunctions, respectively) shall apply to the enforcement of this chapter with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of this chapter or a regulation promulgated under this chapter. The provisions (including penalties) of section 675 of this title shall apply to the performance of official duties under this chapter. Congress finds that (i) the products and activities that are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and (ii) regulation of the products and activities as provided in this chapter is necessary to prevent and eliminate burdens on such commerce and to effectively regulate such commerce.

(Pub.L. 99-198, Title XVII, § 1768(e), Dec. 23, 1985, 99 Stat. 1655.)

LEGISLATIVE HISTORY
P.L. 99-198

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Virus-Serum-Toxin Act of 1913

The bill would clarify and update the Virus-Serum-Toxin Act of 1913 (the "VST Act"), the statutory authority for U.S. Department of Agriculture regulation of animal vaccines and related products.

USDA's Animal and Plant Health Inspection Service ("APHIS") has a long and successful history of assuring livestock owners, veterinarians, and the American public that there is an ample supply of safe and effective animal vaccines and other biological products. APHIS carries out its responsibilities pursuant to the VST Act.

But legislation designed to serve the interest of animal agriculture more than seven decades ago has been overtaken by modern events, due to the VST Act's archaic concepts of authority for a Federal regulatory agency, as compared to modern statutes.

Two recent Federal court decisions have created confusion and concern among the producers of animal biological products and those who utilize them. The thrust of these decisions is that USDA has primary regulatory authority over finished products physically moving in interstate commerce, but all other products, such as those made and sold within a single State, are subject only to Food and Drug Administration jurisdiction. These "intrastate" products are not subject to USDA licensure, and FDA has, so far, not asserted its authority over them in a

comprehensive manner. In the meantime, "interstate" products remain firmly under the jurisdiction of USDA.

The narrow "intrastate" versus "interstate" distinction found in the VST Act no longer exists for any class of comparable products. Federal laws make no such distinctions for human-use pharmaceuticals, animal drugs, food additives, color additives, medical devices, processed food, meat and poultry products, or pesticides; all are subject to uniform Federal regulatory standards, whether they cross state lines or not.

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Animal agriculture has changed drastically since 1913. One major alteration in the industry is the tremendous increase in interstate movement of animal and animal-derived foods. There are truly national markets for the live animals and their products, while USDA's animal vaccine regulatory program is compelled by law to maintain an artificial distinction between "intrastate" and "interstate" commerce in the products used to treat these animals.

The need for uniform national standards has become recognized widely in recent years. The major national livestock producer groups support these amendments, as does the veterinarians' national association. Furthermore, a number of States have enacted rules permitting only USDA-licensed animal vaccines to be sold or used within their borders.

According to a recent USDA survey, at least 15 States now routinely require that animal biologic products used within their boundaries be licensed by USDA, although some of these States permit certain types of unlicensed vaccines under limited special circumstances. These States are Alabama, Colorado, Florida, Hawaii, Idaho, Louisiana, Michigan, Minnesota, Mississippi, Montana, New York, Oklahoma, Pennsylvania, Utah and Wyoming. When the Oklahoma State Board of Agriculture adopted an "emergency regulation" to this effect in 1981, its justification was "an imminent peril to the public welfare." USDA found that only two States, California and South Dakota, actively regulate "intrastate" animal biologics. It must be assumed, therefore, that "intrastate" animal biologic products are almost entirely free of any official scrutiny in the remaining 33 States.

USDA can effectively control the movement of diseased animals and contaminated food of animal origin through court-authorized seizure and injunctive powers. However, the VST Act presently does not give the Department these essential means for the control of animal vaccines and related products. Expanded regulatory authority for USDA would be meaningless, if the Department did not have the tools needed to bring about compliance. Presently, the only enforcement tool is a criminal misdemeanor prosecution. The bill would give USDA powers comparable to those available to regulate commerce in animals and animal-derived foods such as detention and court-ordered seizure and injunction.

The bill provides licensing exemptions for animal owners and veterinarians, who could continue to produce unlicensed vaccines for use in animals under their care

(although enforcement actions against unsafe or ineffective products would be authorized). Biologics produced in States that have adequate testing/regulatory programs could continue to be marketed "intrastate" under those State programs without USDA licensing. In addition, all other "intrastate" manufacturers would have four years from the date of enactment to phase into the USDA licensing system.

9 C.F.R. § 112.2 Final container label, carton label, and enclosure.

* * *

(b) Labels may also include any other statement which is not false or misleading and may include factual statements regarding variable response of different animals when vaccinated as directed but may not include disclaimers of merchantability, fitness for the purpose offered, or responsibility for the product.

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57 Fed. Reg. 38758 (August 27, 1992)

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9 CFR Part 102

[Docket No. 88-187-2]

Viruses, Serums and Toxins and Analogous Products; Restrictions on Distribution and Use

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations pertaining to restrictions which may be imposed by States on the distribution and use of veterinary biological products. It also provides a procedure whereby any person may request that Federal restrictions be imposed on such products. The purpose of the final rule is to clarify the regulations with respect to State restrictions on the use and distribution of veterinary biological products, and to specify how a person can request that Federal restrictions be imposed on such products.

EFFECTIVE DATE: This rule is effective September 28, 1992.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director. Veterinary Biologics, BBEP, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, telephone number (301) 436-8245.

SUPPLEMENTARY INFORMATION:

Background

A proposed rule was published on October 19, 1990 (55 FR 42392, Docket No. 88-187); to clarify APHIS' position that restrictions on the distribution and use of Federally licensed veterinary biological products may be imposed by a State or other jurisdiction when such restrictions are based on local disease conditions. Moreover, the proposed rule provided a procedure whereby any person, including a State or other jurisdiction, may request that Federal restrictions be imposed on such products. A 80-day comment period which ended December 18, 1990, was provided for in that proposal.

The Animal and Plant Health Inspection Service (APHIS) received seventeen comments regarding the proposed rule. Comments were received from State animal health authorities, trade associations, a professional association, veterinary hospitals, universities, a biologics manufacturer, and a biologics consultant. APHIS has carefully considered all comments concerning the proposed rule.

Based on the rationale set forth in the proposed rule and this document, APHIS is adopting the provisions of the proposed rule with two minor changes as discussed below for the purposes of clarity.

Fourteen comments were generally in favor of the rule as proposed. Two comments took exception to the rule. One comment indicated that the proposed rule should be strengthened to require States to seek APHIS approval prior to imposing restrictions on distribution

and use of veterinary biologics. The comments are discussed in greater detail below.

Twelve comments agree that, based on local disease conditions, States should have the authority to impose restrictions on the distribution and use of veterinary biological products.

Nine of these comments indicated that because vaccines used in disease control programs require careful tracking, vaccines in these categories should be administered by or under the direction of a veterinarian. APHIS has the authority to require label statements that certain biological products be used under the supervision of veterinarians and has imposed such requirements (see 9 CFR 102.5(e)).

Several commenters requested that the wording in 9 CFR 102.5(e) which currently reads in relevant part " * * * the biological product is restricted to use by veterinarians, or under the *supervision* of veterinarians, or both" be changed to " * * * by or under the *direction* of a veterinarian" (emphasis added). The commenter argued that the change would be consistent with the language used under labeling requirements in accordance with 9 CFR 112.2(d)(1).

This comment is beyond the scope of this rulemaking and therefore will not be considered in this docket. However, the agency will consider whether it is appropriate to make the suggested changes in future rulemaking.

Several commenters also requested that the language in 9 CFR 102.5(e) and (f) be amended to read that restrictions be based on "the protection of animal or human

health and safety," rather than the language currently used: "the protection of domestic animals or the public health, interest, or safety, or both". The commenters stated that "use of the term 'interest' is vague and unacceptable."

The regulation will not be amended based on these comments because the purpose of the Act is to assure that biologics used in the treatment of animals are pure, safe, potent, and efficacious. The public benefits as a result of the successful protection of animals from various diseases, including those which are of great public concern such as rabies. Since safe and effective vaccines and other biologics are in the public interest, APHIS has used this term in the regulations.

Seven commenters indicated that States should have the authority to add to Federal restrictions, as appropriate, based on a need to protect animal or human health and safety so long as such restrictions do not lessen the effect of Federal regulations. APHIS agrees with the comment that States should not be allowed to lessen the effect of Federal restrictions on the distribution and use of veterinary biological products. APHIS, however, does not agree that States should be allowed to add various restrictions, as appropriate, based upon a need to protect domestic animals or the public health, interest, or safety. Any restrictions, other than those which are necessary to address a local disease condition, should be Federally imposed so that they are uniform nationwide.

The legislative history relating to the 1985 amendments to the Act, which extends USDA's authority over veterinary biologics, clearly expresses Congressional

intent that Federal regulation of veterinary biologics is needed to prevent and eliminate burdens on commerce and that there is a need for uniform national standards regarding these products. Therefore, States are not free to impose requirements which are different from, or in addition to, those imposed by USDA regarding the safety, efficacy, potency, or purity of a product. Similarly, labeling requirements which are different from or in addition to those in the regulations under the Act may not be imposed by the States. Such additional or different requirements would thwart the Congressional intent regarding uniform national standards, and would usurp USDA's authority to determine which biologics are pure, safe, potent, and efficacious. However, it has been APHIS' consistent position that individual States may impose certain restrictions on the distribution and use of biological products licensed by USDA based on local disease conditions when such restrictions are made on a product-by-product basis. For example, a State is permitted to restrict distribution of a biological product where a particular disease does not exist in the State and where use of the biological product would make it difficult to distinguish between exposed and vaccinated animals.

Likewise, a State is permitted to restrict use of a product to licensed veterinarians when a disease exists in the State and the State has an active eradication program. In this case, such a restriction may be necessary to ensure the effectiveness of the eradication program.

Other commenters asked that only States and not other jurisdictions should be allowed to impose the restrictions in § 102.5(d)(2), and that the restrictions be

imposed on a case-by-case basis. The term "other jurisdiction" must remain in the regulations because the term "States" does not include places under Federal jurisdiction. Insofar as other localities are concerned, it is APHIS' position that any restrictions based on local disease conditions within a State should be imposed by or in conjunction with State authorities in order to prevent a proliferation of conflicting restrictions.

Two commenters disagreed that any person should be able to request that Federal restrictions be imposed on biologics. The commenters were concerned that such a provision in the rules might encourage individuals to attempt to restrict unnecessarily the use and availability of veterinary biological products. With respect to the provision in the final rule which allows any person to request APHIS to impose a Federal restriction on biologics, we do not believe that such requests should be limited to State agencies. The commenters' concern is unwarranted because APHIS would be making the decision regarding such requests, and unnecessary restrictions would not be imposed on products.

Two minor changes are made to § 102.5(d)(2) for clarity. The term "Deputy Administrator" is changed to "Administrator" to be consistent with APHIS administrative policy and the term "shall" is changed to "may".

Executive Order 12291, Executive Order 12778, and Regulatory Flexibility Act

We are issuing this final rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the

Department it has been determined that this final rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions, and will not have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule does not preempt any State or local laws, regulations, or policies, where they are necessary to address local disease conditions or eradication programs. However, where safety, efficacy, purity, and potency of biological products are concerned, it is the agency's intent to occupy the field. This includes but is not limited to the regulation of labeling. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products. There are no administrative proceedings which must be exhausted prior to any judicial challenge to the regulations under this rule. Under certain circumstances, States may restrict the distribution and use, within their own borders, of veterinary biological products licensed by APHIS. The current regulation, however, has caused some confusion regarding the extent of such restrictions. The final rule

clarifies the regulation. It also provides a procedure whereby any person can request that Federal restrictions be imposed on a veterinary biologic.